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(54) Specimen collection assembly with cap

(57) The present invention is a collection assembly (10) comprising a container (12), and a cap assembly (14) removably and sealably secured to the container (12) whereby access to the interior of the container (12) can be made with a piercing element without removing the cap assembly (14) from the container (12). The cap assembly (14) includes a cap body and a membrane-like septum (32) supported by the cap body. The septum (32) provides for a pierceable element to have access to the interior of the container. The membrane is of a thermoplastic elastomer and is self-sealing upon removal of the piercing element.

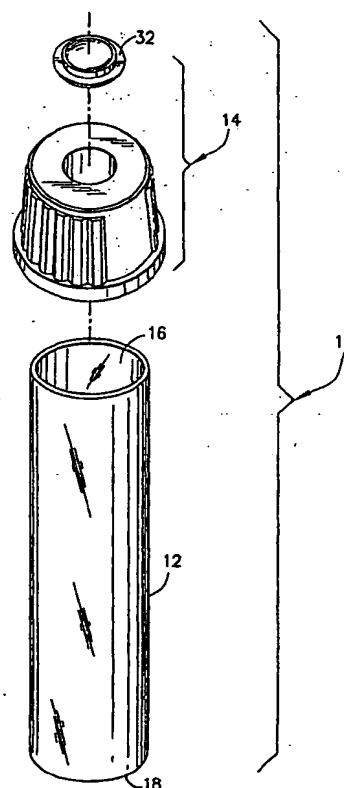


FIG.2

## Description

### BACKGROUND OF THE INVENTION

#### 1. Field of the Invention

[0001] The present invention relates to a collection assembly and more particularly to a microcollection container and cap assembly suitable for collecting small quantities of a specimen such as blood from a patient, that provides access to the interior of the container without the need for removing the cap from the assembly and for maintaining a specimen in secure fashion for subsequent testing.

#### 2. Description of Related Art

[0002] Analytical instrumentation has made it possible to carry out a variety of hemological diagnostic procedures on very small quantities of blood. The blood may be collected from a small puncture placed in a patient's finger or ear lobe. The blood is collected in a microcollection container. Once the small quantities of blood are collected, the container is sealably covered by a cap.

[0003] In order for a laboratory technician to conduct tests on the blood sample which is collected in the container, the cap must be removed from the container so as to provide access to the blood sample. In the alternative, the entire contents of the container may be transferred from the container to an instrument compatible sample holder in order for laboratory analysis to take place.

[0004] Therefore, there is a need for a microcollection container that is (i) compatible with instruments for laboratory analysis whereby the specimen does not have to be transferred out of the container for analysis to be conducted; (ii) provides a resealable portion for easy access into the container by a needle or probe that also prevents specimen leakage out of the container; (iii) maintains a specimen in secure fashion; and (iv) prevents contamination to the specimen and to the user.

### SUMMARY OF THE INVENTION

[0005] The present invention is a collection assembly comprising a container and a cap.

[0006] The container includes an open end, a closed end and a cylindrical wall therebetween which preferably comprises the interior of the container for accommodating the specimen.

[0007] Desirably, the cap comprises a cap body removably sealably secured to the open end of the container. The cap body supports a membrane for providing resealable access to the interior of the container. The membrane is formed of a material which is capable of being pierced and resealed on a repetitive basis with a needle or instrument probe. Most preferably, the mem-

brane is formed of a thermoplastic elastomer. Such thermoplastic elastomer includes isoprene propylene, such as MONOPRENE (a trademark of QST, Inc.) sold by QST, Inc., St. Albans, Vermont.

5 [0008] Preferably, the membrane is disc-shaped having a concave surface facing away from the container interior which assists in resealing of the membrane. The thermoplastic elastomer allows for the resealing of the pierced membrane in a manner which prevents specimen leakage therethrough even when the collection assembly is held in an inverted position.

10 [0009] Preferably, the cap body includes a top portion, a bottom portion, a cylindrical sidewall extending from the top portion to the bottom portion having an inner surface and an outer surface, an access passageway at the top portion and a membrane supported across the passageway.

15 [0010] The cap body may further include a depending annular skirt extending into the interior of the container from the top portion and defining an annular region with the cylindrical sidewall. The open end of the container is accommodated within the annular region. The depending skirt includes an access passageway, with the membrane being supported across the passageway.

20 [0011] Preferably, the membrane and the cap body may be co-injection molded or insert molded.

25 [0012] An advantage of the present invention is that it facilitates direct access to a sample for diagnostic instrumentation systems and enables microcollection container compatibility with diagnostic instrumentation by providing features such as pierceability and self-resealing of the cap.

30 [0013] Still another advantage of the present invention is that the self-sealing pierceable cap permits mixing of the specimen in the container without transferring the specimen to another container and providing for direct access to the specimen via the self-sealing pierceable cap by diagnostic instrumentation.

35 [0014] Most notably, is that the present invention permits a specimen to be accessed through the top of the cap without removing the cap from the container, thereby providing minimal exposure of the specimen to the user.

40 [0015] In addition, the present invention permits the assembly to be directly used on instrumentation similar to that used for evacuated collection assemblies.

45 [0016] Advantages of the membrane of the present invention include that: (i) it can be pierced and resealed many times; (ii) it requires less than 21b. force for a probe or needle to pierce it; and (iii) the concave shape aids in the ability of the membrane to seal properly after the piercing element is removed.

### DESCRIPTION OF THE DRAWINGS

50 [0017] FIG. 1 is a front plan view of the collection assembly of the present invention.

[0018] FIG. 2 is a perspective view of the collection

assembly of FIG. 1 illustrating the container, the cap and the membrane.

[0019] FIG. 3 is a cross sectional view of the collection assembly of FIG. 1.

[0020] FIG. 4 is a side elevational view, partially in section of the collection assembly of FIG. 3.

[0021] FIG. 5 illustrates the collection assembly of FIG. 4, with a probe extending thereinto.

#### DETAILED DESCRIPTION

[0022] Referring to the drawings in which like reference characters refer to like parts throughout the several views thereof, FIGS. 1-3 illustrate the collection assembly 10 of the present invention.

[0023] Collection assembly 10 includes a container 12 and a cap assembly 14. Cap assembly 14 may be removably secured to the container.

[0024] Container 12 is an elongate member having an open upper end 16, a lower end 18 including a rounded closed bottom 19 and a cylindrical wall 20 extending therebetween. The cylindrical wall 20 defines an interior 17 internally thereof for accommodating a specimen such as a blood specimen. The cylindrical wall 20 extends beyond the rounded closed bottom 19 to form an annular extension 22 which permits container 12 to stand upright on a flat surface. Once a liquid specimen, such as blood is collected in interior 17 of the container, the container may be sealingly closed by cap assembly 14.

[0025] Referring to FIG. 4, cap assembly 14 includes a cap body 30 and a septum 32 supported by cap body 30. Cap body 30 is preferably an integrally formed molded plastic member generally in the shape of an inverted cup. The cap includes a flat upper surface 34, an opposed open lower surface 36 and a cylindrical sidewall 38 extending therebetween. Cylindrical side wall 38 includes a plurality of inwardly directed protrusions 40 which engage an exterior surface of cylindrical wall 20 of the container about open upper end 16 to provide sealed engagement between cap body 30 and container 12.

[0026] Upper surface 34 includes an open upper extent 44 and a central passageway 45 which provides access through cap body 30 and into interior 17 of container 12.

[0027] Septum 32 is a disc-like membrane formed of a thermoplastic elastomer. As shown in FIG. 4, septum 32 includes a generally planar portion 50 and an upwardly extending annular ridge 52. Annular ridge 52 has a diameter which allows it to be force fitted within the open upper extent 44 and retained in sealed engagement therewith. Planar portion 50 of septum 32 defines a flat planar surface which faces towards the interior of container 12. Annular ridge 52 defines a concave surface 53 in opposition to planar surface 50. Septum 32 defines a centrally located portion 54 having a thickness of about .028 inches. The central portion allows the sep-

tum to be easily pierced by a piercing element to extract a portion of the sample from interior 17 of container 12.

[0028] In use, a liquid sample is collected in container 12. Cap assembly 14 is sealably secured to the open upper end of container 12. Then, as shown in FIG 5, a piercing element 60 is inserted into container 12 by inserting element 60 through passageway 45 defined through cap body 30. Distal tip 62 of element 60 then pierces through septum 32 at central portion 54. Since the material of septum 32 is a thermoplastic elastomer, septum 32 is easily pierced by low insertion forces whereby even for a relatively wide element 60 having a diameter of about .0625 inches, central portion 54 of septum 32 may be pierced by a force of less than 2 pounds.

[0029] Insertion of element 60 continues until it reaches the sample in interior 17 of container 12 and then element 60 collects a portion of the sample. Element 60 is then removed by withdrawing it back through passageway 45 in cap body 30. Upon withdrawing element 60 from septum 32, the septum self-seals. Due to the thermoplastic elastomer material and that septum 32 has a flat planar surface 50 facing the interior of container 12 and opposed concave surface 53 facing in opposition thereto, helps reseal a hole placed in septum 32 by element 60.

[0030] The septum shape defines a concave surface in the direction of the element withdrawal. The compressive forces exerted by such a shape to effect resealing of any hole placed therein as element 60 is withdrawn from the container. Thus, septum 32 reseals after multiple puncture sites have been placed therein. The sample in container 12 can be repeatedly sampled with the septum self-sealing upon each portion extraction.

[0031] The collection assembly of the invention may be made of a molded thermoplastic material so that the specimen collected may be readily viewed. Representative materials include, for example, polyethylene, polypropylene and polyvinyl chloride. The collection container may incorporate a hydrophilic material or a silicon, or a texture may be applied to the internal surface thereof for enhancing the flow and mixing of blood introduced into the container.

[0032] Although it is within the purview of the invention to provide caps which are colored to defined specific forms of fluid collection containers containing materials for one reason or another or for defining the kind of examination to be conducted on the specimen collected, transparent caps may be provided. Also, it should be noted that the dimensions of the container are such as to provide space for labeling which may be important for identifying the collected specimen.

#### Claims

1. A specimen collection assembly comprising:

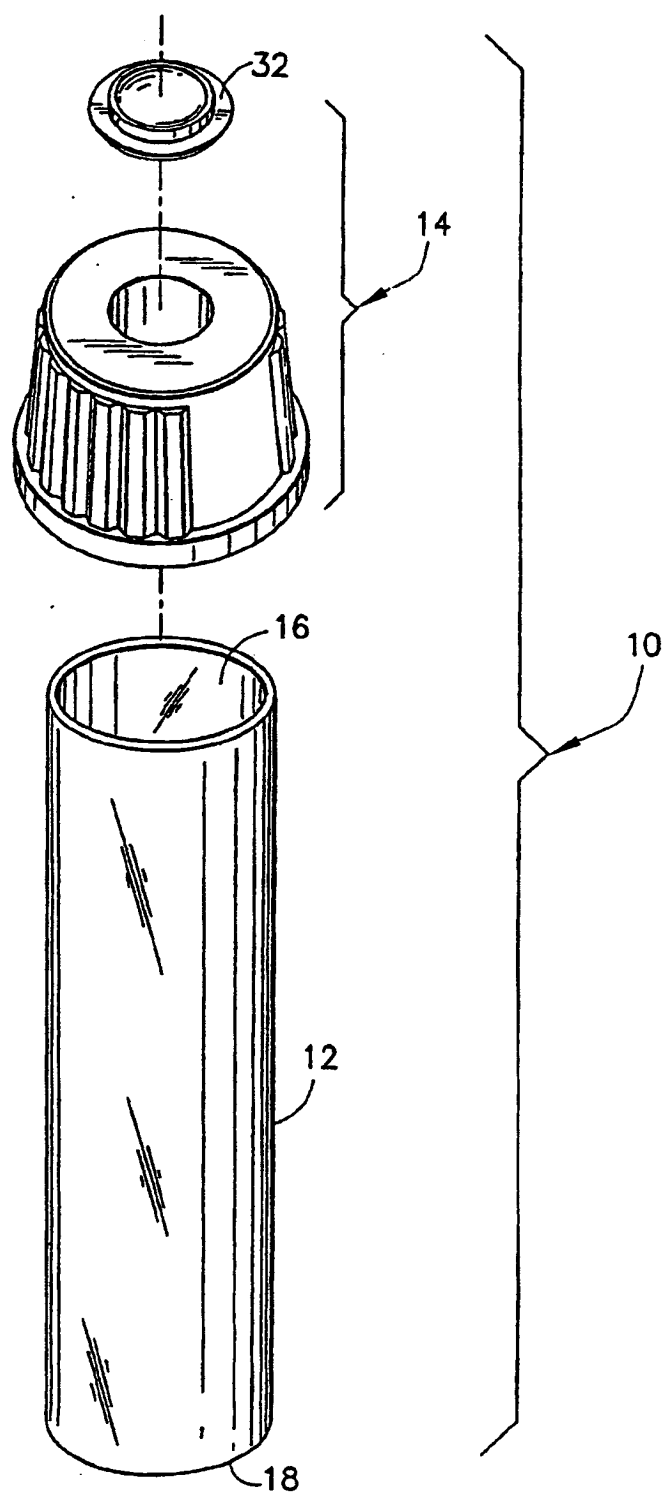


FIG. 2

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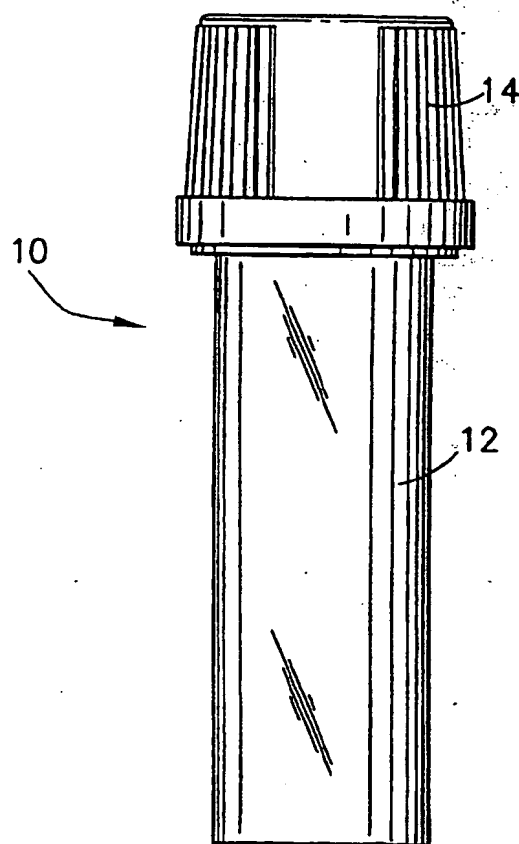


FIG.1

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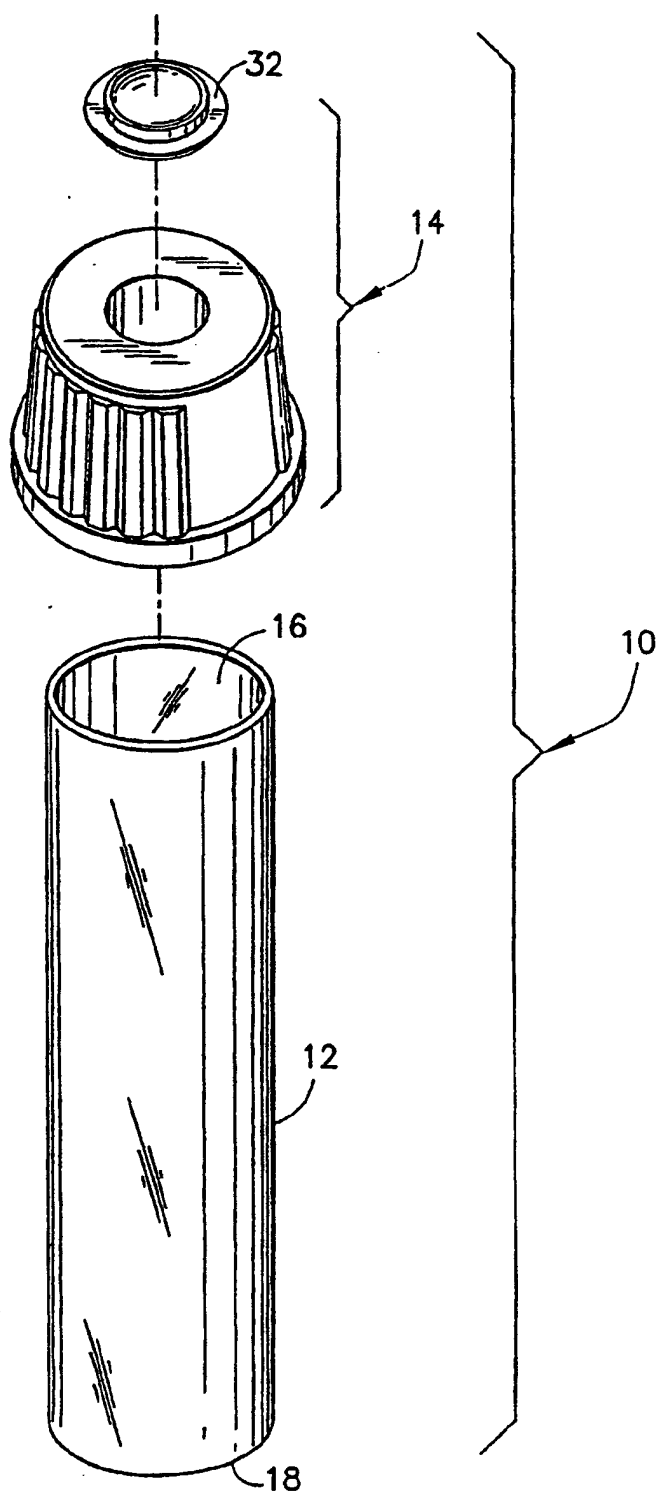


FIG.2

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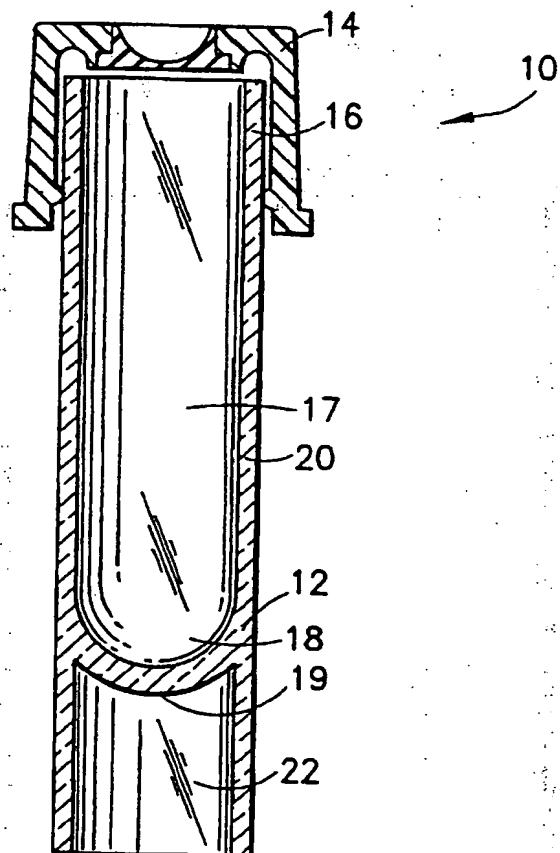


FIG.3

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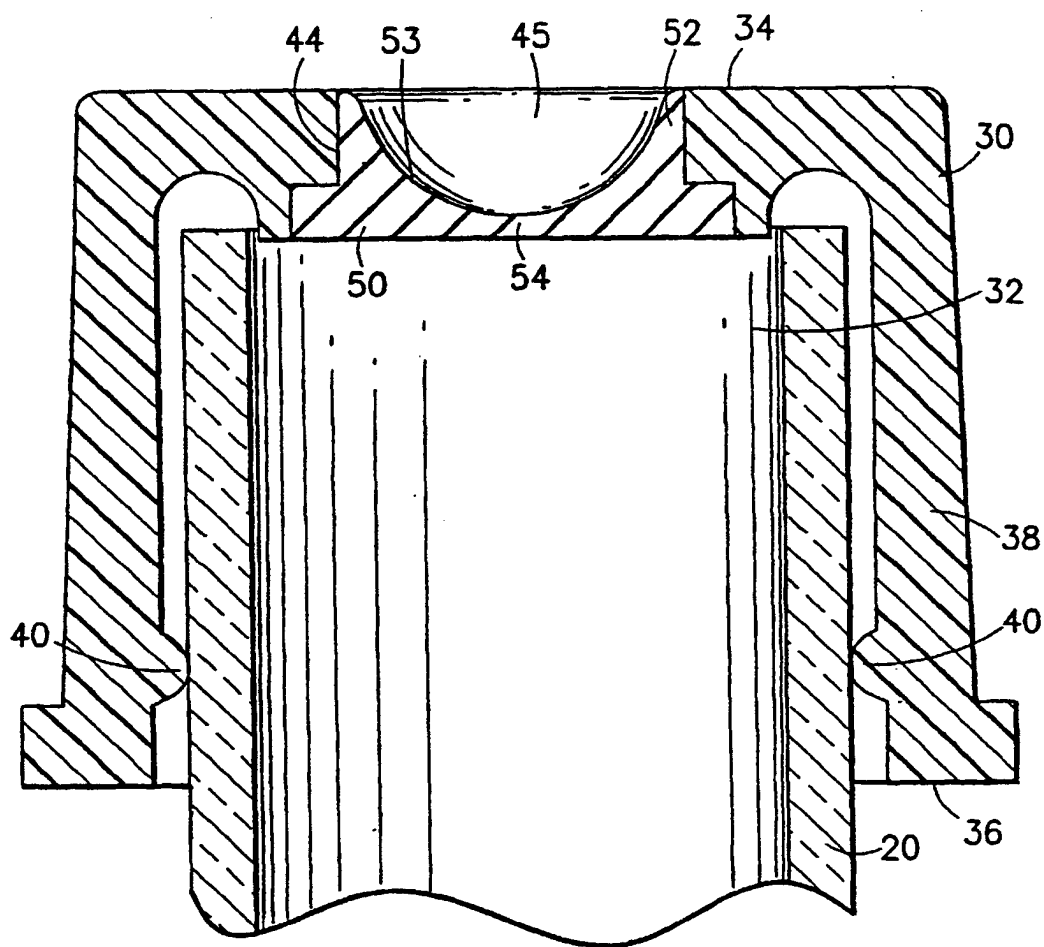


FIG.4

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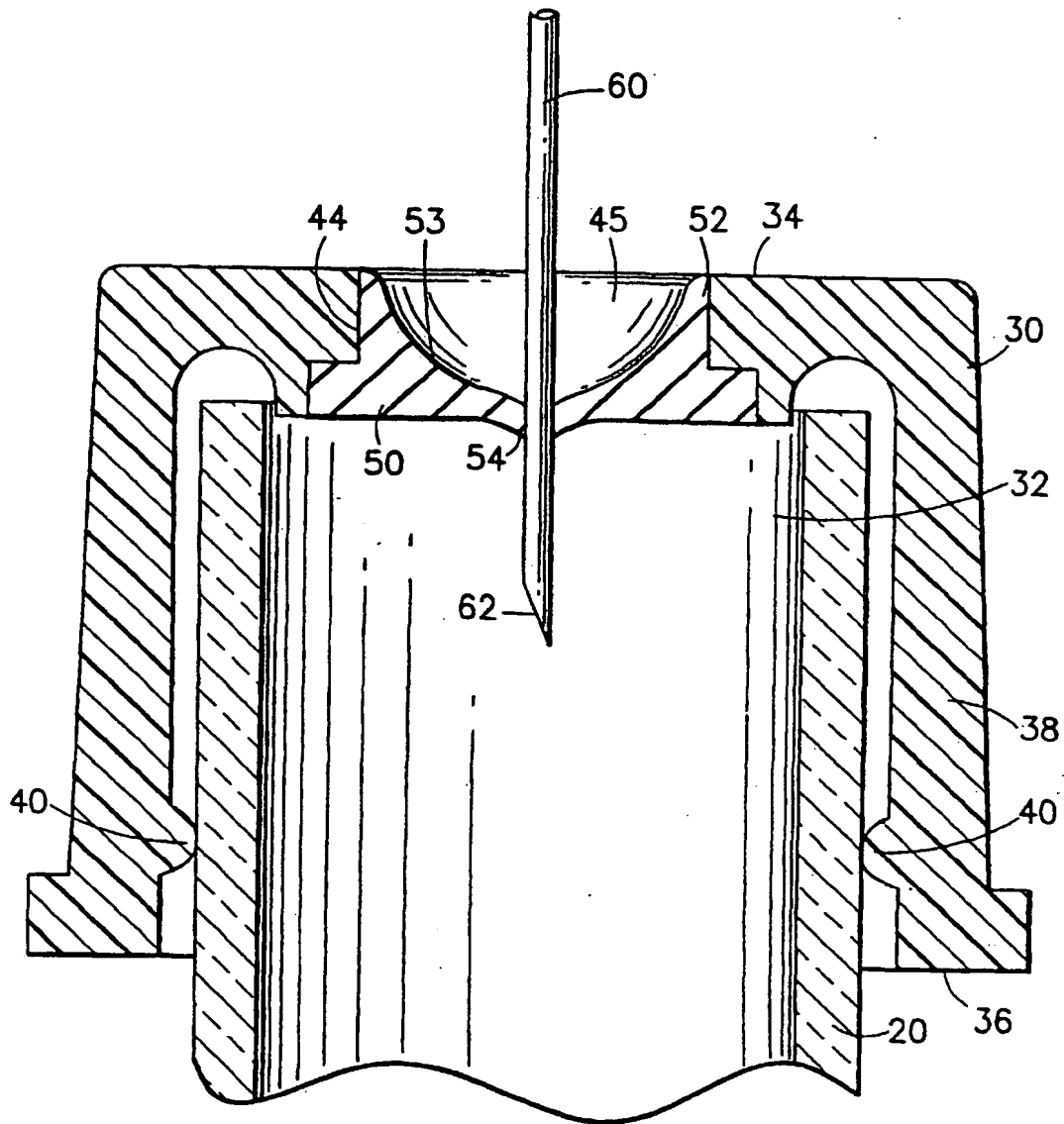
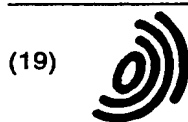


FIG.5

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- **Prais, Alois**  
**Rutherford, New Jersey 07070 (US)**

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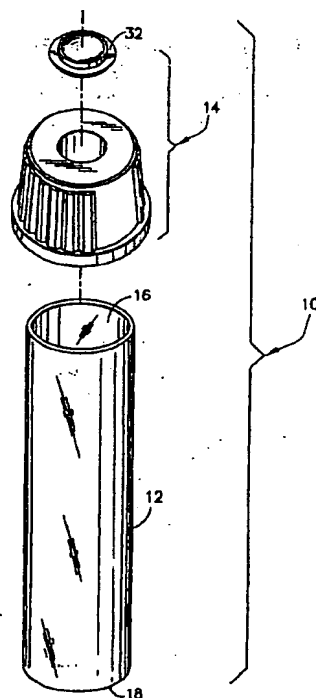
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**FIG.2**

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# EUROPEAN SEARCH REPORT

Application Number  
EP 00 11 3635

DOCUMENTS CONSIDERED TO BE RELEVANT			
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int.Cl.7)
X	US 5 306 270 A (MACARTNEY CHARLES T ET AL) 26 April 1994 (1994-04-26) * column 2, line 5 - column 3, line 18 * * column 2, line 38 - column 3, line 15; claim 1; figures 1,2 * * abstract *	1	B01L3/14
X	US 5 779 074 A (BURNS JAMES A) 14 July 1998 (1998-07-14) * column 2, line 7 - column 2, line 63 * * column 7, line 43 - column 7, line 58; figure 11 * * column 10, line 46 - column 10, line 63 *	1	
X	WO 89 02399 A (PARSONS JOSEPH NOMINEES) 23 March 1989 (1989-03-23) * page 7, line 23 - page 9, line 27; figure 2 *	1	
X	EP 0 454 493 A (DAYKIN VICTOR ALEXANDER ;MACARTNEY CHARLES TERENCE (CA)) 30 October 1991 (1991-10-30) * page 1 * * column 1, line 37 - column 1, line 57 * * column 3, line 4 - column 3, line 8 * * column 4, line 30 - column 4, line 56; figures 4,5 *	1	
A	US 5 247 015 A (BAYAN GHAWAMEDIN) 21 September 1993 (1993-09-21) * column 3, line 28 - column 6, line 46; claim 1 *	1	TECHNICAL FIELDS SEARCHED (Int.Cl.7)  B01L B65D
The present search report has been drawn up for all claims			
Place of search <b>MUNICH</b>		Date of completion of the search <b>7 May 2002</b>	Examiner <b>Smith-Hewitt, L</b>
CATEGORY OF CITED DOCUMENTS X : particularly relevant if taken alone Y : particularly relevant if combined with another document of the same category A : technological background O : non-written disclosure P : intermediate document		T : theory or principle underlying the invention E : earlier patent document, but published on, or after the filing date D : document cited in the application L : document cited for other reasons & : member of the same patent family, corresponding document	

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**ANNEX TO THE EUROPEAN SEARCH REPORT  
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EP 00 11 3635

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